510(k) Summary

JUN - 4 2010

Sponsor: Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
(906) 225-5602
Contact: Emily M. Downs

Prepared May 20, 2010

Device Name: Pioneer Poise Anterior Cervical Plate System

Classification Name: The classification of the Pioneer Poise Anterior Cervical Plate System is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3060: Spinal intervertebral body fixation orthosis.

Product Codes: The product code is KWQ. The Panel code is 87.

Predicate Device: K083663- Pioneer Anterior Cervical (PAC) Plate System (SE 2/25/09)
K072703- Pioneer SlimFuse Anterior Cervical Plating System (SE 1/10/08)
K053053- Pioneer Anterior Cervical Plate System (SE11/16/05)
K043066- Pioneer Anterior Cervical Plate System (SE 2/3/05)

Description: The Pioneer Poise Anterior Cervical Plate System consists of an assortment of plates and screws. The screws are used to secure the plates to the vertebral bodies of the cervical spine through an anterior approach. The Poise system consists of static and dynamic plates in lengths that range from 10-84mm and include one, two, three and four level designs. The dynamic design provides for uni-directional axial movement for postoperative load sharing between the plate and graft. The plates have an integrated screw retention mechanism. Screws range from 10-20mm in length, 4.0 or 4.5mm in diameter, and are available in self tapping or self drilling. The plates and screws are manufactured from Titanium alloy (ASTM F136) and Nitinol (ASTM F2063).

The system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

Intended Use: The Pioneer Poise Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Comparison to Predicate Devices:	The subject device has indications for use identical to those of the predicate PAC system and employs the same principles of operation. Identical materials are used for both subject and predicate plates and screws. Available screw lengths (10-20mm), screw diameters (4.0/4.5mm), overall plate length (10-84mm), and plate types (one, two, three and four level; static and dynamic) are identical for both systems.
Material:	The Pioneer Poise Anterior Cervical Plate System plates and screws are manufactured from titanium alloy (Ti6Al4V ELI, according to ASTM F136). The plates incorporate a screw-retention mechanism ("spring"), which is manufactured from Nitinol (ASTM F2063).
Non-Clinical Performance Data:	Mechanical testing was presented to characterize construct and component performance, including testing static and fatigue compression bending and static torsion per recognized ASTM F1717, axial pullout screw strength per ASTM F543, and additional testing performed per internal protocols to assess screw pull through plate and screw retention characteristics. The test results of verification testing demonstrate that the mechanical performance of the Pioneer Poise Anterior Cervical Plate System is substantially equivalent to the predicate devices.
Performance and SE Determination:	Comparisons of device performance data, materials, indications and design/function to predicate devices were provided in making a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Pioneer Surgical Technology
% Ms. Emily M. Downs
375 River Park Circle
Marquette, Michigan 49855

Re: K100708
Trade/Device Name: Pioneer Poise Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 13, 2010
Received: April 14, 2010

Dear Ms. Downs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

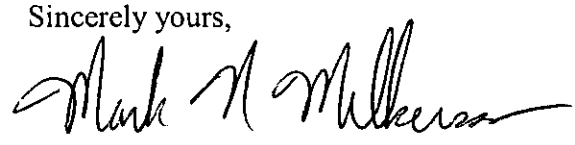
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):	K100708
Device Name:	Pioneer Poise Anterior Cervical Plate
Indications for Use:	The Pioneer Poise Anterior Cervical Plate System is intended for anterior cervical fixation for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100708